METHOD AND DEVICE FOR LEFT ATRIAL APPENDAGE OCCLUSION

This is a continuation-in-part of U.S. Patent Application No. 09/187,200, filed November 6, 1998, the disclosure of which is incorporated in its entirety herein by reference. (now U.S. Pat No. 6,152,144,

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Background of the Invention

Embolic stroke is the nation's third leading killer for adults, and is a major cause of disability. There are over 700,000 strokes per year in the United States alone. Of these, roughly 100,000 are hemoragic, and 600,000 are ischemic (either due to vessel narrowing or to embolism). The most common cause of embolic stroke emanating from the heart is thrombus formation due to atrial fibrillation. Approximately 80,000 strokes per year are attributable to atrial fibrillation. Atrial fibrillation is an arrhythmia of the heart that results in a rapid and chaotic heartbeat that produces lower cardiac output and irregular and turbulent blood flow in the vascular system. There are over five million people worldwide with atrial fibrillation, with about four hundred thousand new cases reported each year. Atrial fibrillation is associated with a 500 percent greater risk of stroke due to the condition. A patient with atrial fibrillation typically has a significantly decreased quality of life due, in part, to the fear of a stroke, and the pharmaceutical regimen necessary to reduce that risk.

For patients who develop atrial thrombus from atrial fibrillation, the clot normally occurs in the left atrial appendage (LAA) of the heart. The LAA is a cavity which looks like a small finger or windsock and which is connected to the lateral wall of the left atrium between the mitral valve and the root of the left pulmonary vein. The LAA normally contracts with the rest of the left atrium during a normal heart cycle, thus keeping blood from becoming stagnant therein, but often fails to contract with any vigor in patients experiencing atrial fibrillation due to the discoordinate electrical signals associated with AF. As a result, thrombus formation is predisposed to form in the stagnant blood within the LAA.

Blackshear and Odell have reported that of the 1288 patients with non-rheumatic atrial fibrillation involved in their study, 221 (17%) had thrombus detected in the left atrium of the heart. Blackshear JL, Odell JA., Appendage Obliteration to Reduce

FIG. 28 is a perspective view of a further embodiment of the present invention.

FIG. 29 is a side elevational view of the embodiment of FIG. 28.

Figs. 30 and 30A are views
~~FIG. 30 is a~~ perspective ~~view~~ of a further occlusion device in accordance with the present invention.

FIG. 31 is an end view taken along the line 31-31 of FIG. 30.

FIG. 32 is a schematic illustration of an inflatable balloon positioned within the occlusion device of FIG. 30.

FIG. 33 is a schematic view of a pull string deployment embodiment of the occlusion device of FIG. 30.

FIGS. 34A and 34B are side elevational schematic representations of partial and complete barrier layers on the occlusion device of FIG. 30.

FIG. 35 is a side elevational schematic view of an alternate occlusion device in accordance with the present invention.

FIG. 36 is a schematic view of a bonding layer mesh for use in forming a composite barrier membrane in accordance with the present invention.

FIG. 37 is an exploded cross sectional view of the components of a composite barrier member in accordance with the present invention.

FIG. 38 is a cross sectional view through a composite barrier formed from the components illustrated in FIG. 37.

FIG. 39 is a top plan view of the composite barrier illustrated in FIG. 38.

Detailed Description of the Preferred Embodiment

FIGS. 1-3 show an embodiment of an occluding device 10 having features of the invention where an occluding member 11 is secured to a retention member 12 that is arranged to fix the occluding member in a desired position within a body passageway or cavity. The occluding member 11 generally has disc shape with an outer rim 13 around the perimeter of a frame structure 14 which supports a barrier 15. The outer rim 13 can be circular or polygonal, or any other shape that is suitable for conforming to the inside surface of a body cavity. A hub 16 can be located near the center of the occluding member 11 which serves to connect the retention member 12 to the occluding member, in addition to other functions. The outer rim 13 is typically made from a soft polymer material 17 which permits flexibility of the outer rim and facilitates sealing of the outer